

REMARKS

Claims 1, 5, 11 and 16 are amended. Claims 18-23 are added. Claims 1, 2, 5, 7, 9, 11, 12, 16 and 18-23 are pending in the application.

The specification stands objected to based on various grounds with appropriate correction requested by the Examiner. With respect to the typographical errors on page 13, such have been amended. The specification has additionally been amended to include sequence identification numbers as appropriate when referring to specific nucleotide sequences. The discussions of Figs. 1, 4, 6, 7, 10 and 11 are amended to correctly refer to identification and/or labels present in the corresponding figures.

With respect to the Examiner's indication regarding the presence of embedded hyperlinks within the specification, applicant notes that the hypertext transfer protocols indicated are not between symbols "< >", and are not browser-executable as referred to in MPEP § 608.01. However, without admission as to the propriety of the objection, the internet site addresses have been deleted as required by the Examiner.

Claims 5 and 16 stand objected to based on informalities. The word "the" preceding the word "claim" in claim 5 is deleted as suggested by the Examiner. With respect to claim 16, such is amended to no longer recite a sequence which codes for a promoter. Accordingly, applicant respectfully requests withdrawal of the objections to claims 5 and 16 in the Examiner's next action. Applicant notes that since there are no rejections set forth with respect to claim 16 the amendment to overcome the objection of such claim places claim 16 in condition for immediate allowance.

Claims 1, 5, 7, 9, and 11 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention. The Examiner indicates at page 4 of the present action that the rejection is based upon the recitation in claims 1 and 11 of an isolated polynucleotide having at least 70% sequence identity with SEQ ID NO.: 1 and proteinase inhibitor 1 (pin 1) gene promoter activity. The Examiner indicates that such recitation implies a polynucleotide having a percent identity with a promoter activity. Without admission as to the propriety of the Examiner's statements, claims 1 and 11 are amended to insert the word "having" as suggested by the Examiner. Accordingly, applicant respectfully requests withdrawal of the § 112, second paragraph, rejection of claims 1, 5, 7, 9 and 11 in the Examiner's next action.

Claims 1, 2, 5, 7, 9, 11 and 12 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention at the time the application was filed. Such claims stand additionally rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement. The Examiner indicates at page 6 of the present Action that the specification does not describe sufficient isolated polynucleotide sequences having at least 70% sequence identity to SEQ ID NO.: 1 or provide sufficient information concerning which nucleotides within SEQ ID NO.: 1 may be changed. The Examiner further indicates that the specification does not sufficiently describe any fragments of SEQ ID NOS.: 1-3 that retain pin 1 gene promoter activity, and that such alleged insufficiencies cause non-compliance with § 112, first paragraph. The Examiner acknowledges that the specification is enabling for a promoter having SEQ ID NO.: 1, 2 or 3 but indicates that such does not reasonably provide enablement for isolated

polynucleotides having at least 70% identity to SEQ ID NO.: 1 or fragments of SEQ ID NOS.: 1-3 as recited in the claims. Applicant disagrees with the examiner's position and respectfully requests reconsideration.

As indicated at page 16, lines 1-5 of the specification, functional elements of the promoters can be identified using methods known to those skilled in the art and subclones corresponding to functional fragments can be identified by operable linkage to screenable markers and testing utilizing transformed cells. Accordingly, one skilled in the art could identify and/or produce the polynucleotide molecules recited in the claims without undo experimentation. Accordingly, claims 1, 2, 5, 7, 9, 11 and 12 are fully enabled by the specification as written.

With respect to the adequacy of the written description, the Examiner indicates that applicant's specification fails to describe all of the sequences with SEQ ID NO.: 1, SEQ ID NO.: 2 and SEQ ID NO.: 3 that are essential to their promoter activities. However, nowhere is there a requirement that applicant identify each and every location within a promoter sequence which is essential to promoter activity. Clearly, as indicated in applicant's specification, one skilled in the art could produce an isolated polynucleotide having 70% identity to SEQ ID NO.: 1 and/or fragments of SEQ ID NOS.: 1, 2, or 3 which comprise promoter activity. Accordingly, it would be clear to one skilled in the art that the inventor had possession of the claimed polynucleotide sequences at the time the application was filed.

In support of applicant's position that the specification fully complies with the written description and enablement requirements of § 112, applicant submits herewith exemplary issued patents for consideration by the Examiner. These patents, Weigel, U.S. Patent No.

6,239,329; Sakai, U.S. Patent No. 6,489,104; Ohl, U.S. Patent No. 6,262,344; Prieto-Dapena, U.S. Patent No. 6,759,570; and Abrahmsen, U.S. Patent No. 6,723,553, each have allowed claims which recite a percent identity or a fragment of an indicated promoter sequence. Applicant submits these exemplary patents for comparison purposes only and requests that the Examiner consider the extent of each of these disclosures which were found to be enabling and to meet the written description requirement in full compliance with § 112. After such consideration, it is respectfully requested that applicant be afforded equal treatment and equal protection of the laws as provided to the owners of each of the exemplary patents submitted herewith, in accordance with the United States Constitution. Additional patents having allowed claims directed to homologous sequences and fragments of promoters can be provided if the Examiner feels such is warranted.

For at least the reasons discussed above, claims 1, 2, 5, 7, 9, 11 and 12 are in compliance with 35 U.S.C. § 112. Accordingly, applicant respectfully requests withdrawal of the § 112 rejection of such claims in the Examiner's next action.

New claims 18-23 do not add "new matter" to the application since each is fully supported by the specification as originally filed. Claims 18-23 are based upon the claims as originally filed and recite isolated polynucleotides comprising one of SEQ ID NOS.: 1, 2, or 3. Since the Examiner acknowledges enablement and sufficient description of SEQ ID NOS.: 1, 2 and 3 (pages 6-7 of the present Action, and the lack of rejection of claim 16), new claims 18-23 recite allowable subject matter and are in condition for immediate allowance.

For the reasons discussed above, claims 1, 2, 5, 7, 9, 11, 12, 16 and 18-23 are allowable. Accordingly, applicant respectfully requests formal allowance of such pending claims in the Examiner's next action.

Respectfully submitted,

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Enclosures: Copy of U.S. Patent Nos. 6,723,553 B2, 6,759,570 B1, 6,489,104 B1 and 6,262,344 B1